Regulatory Services in Canada

Regulatory Affairs Services Provider in Canada

Health Canada ensures safe and timely access to medicinal products, including medical devices, drugs, and biologics, for the public. The Health Products and Food Branch (HPFB) oversees and controls medicinal product review, assessment, and regulation. The regulatory requirements for obtaining marketing authorization are different for new drugs, medical devices, natural health products, and emergencies and orphan drugs. Each product must obtain its own license that should be compliant with the Good Manufacturing Practices (GMP) requirements and Canada's Good and Drugs Act. Generic product applicants must submit an Abbreviated New Drug Submission (ANDS) that requires less information compared to the New Drug Submission (NDS) which must be submitted for new drug applications. The Marketed Health Products Directorate is responsible for monitoring adverse drug reactions and medication incident data as part of the pharmacovigilance services system. Foreign and local manufacturers and importers must submit information regarding adverse reactions including medical device incidents. This is also applicable to clinical trial sponsors. Therefore, the pharmacovigilance and regulatory affairs procedures surrounding medicinal products can be complex and comprehensive for manufacturers to navigate through.

Why Choose DDReg for Health Canada Regulatory Consulting Services

DDReg's Health Canada Regulatory Services provides ongoing support and development of customized strategies during all regulatory phases while keeping track of the most recent regulatory requirements to ensure high quality and timely submissions. We deliver reliable safety measures, ensure risk mitigation, and collaborate with experts to facilitate effortless delivery of product launches, regulatory filings, and market authorizations. Our specialized expertise includes navigating the intricacies of Medical device registration with Health Canada, ensuring compliance with device classification and licensing requirements (MDEL/MDL).

Our Health Canada Regulatory Consulting Services Portfolio Covers:

- Health Canada Regulatory Affairs Consulting
- Regulatory Strategies and Expert Views
- Regulatory Due Diligence
- Gap Analysis and Remediation
- New Product Authorizations
- Post Approval Life Cycle Management
- CMC Advisory

Country Specific Services

- Regulatory
- Pharmacovigilance
- Labeling
- IPR Support
- Clinical Trial Regulatory
- Medical Devices regulatory services

Our Regulatory Affairs Consulting Services in Canada portfolio covers:

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Regulatory Strategies

The pharmaceutical industry operates under stringent regulations to ensure the safety,... efficacy, and quality...

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New Product Marketing Authorizations

Navigating marketing authorization is a complex and time-sensitive process. Every...

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Gap Analysis and Remediation

In the highly regulated pharmaceutical industry, maintaining compliance is critical...

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Regulatory Due Diligence

Regulatory issues arise unexpectedly and can create significant strain on a company's...

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API & DMF services

Drug Master Files (DMFs) contain confidential and detailed information regarding API...

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CMC Advisory

DDReg's CMC services are dedicated to assisting customers in developing robust and an...

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Post Approval Life Cycle Management

Maximize product value with expert pharma lifecycle management. Our dedicated tea...

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Certification Services

Partner with DDReg to navigate the complex process of regulatory certification of pharmaceutical...

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ANDA and MA Holder Services

Our comprehensive services support both Abbreviated New Drug Applications (ANDA) and...

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